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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,409	08/24/2006	Jeffrey A. Ledbetter	3090641458P3US	3616

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,409	LEDBETTER ET AL.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-413* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-413* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-413 are all the pending claims for this application.

2. The examiner gratefully acknowledges the telephone discussion with Ms. Katherine Neville of June 8, 2008 in order to advance examination on the merits. The numerous species of antibodies encompassed by the protein claims was discussed. Applicants are requested to elect a single preferred protein embodiment for initial examination and which specifically identifies the antigen recognition site, the hinge region, linkers, and the CH1, CH2 and/or CH3 domains, and any amino acid modifications to any one or more of the foregoing regions. These regions can be identified by text or reference to sequence identifiers. Because of the breadth of actual antibody embodiments and the complexity and burden of examining their entire scope, Applicants compliance with this request is gratefully appreciated. The same request is made of Applicants for any polynucleotide or method claim inventions that may be elected and that read on a binding domain immunoglobulin fusion protein.

Lack of Unity: Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to binding domain immunoglobulin fusion proteins comprising a binding domain for a cognate structure such as an antigen, a counter-receptor or the like, a wild-type IgG, IgA or IgE hinge acting region or a mutant IgG1 hinge region having zero, one or two cysteine residues, and immunoglobulin CH2 and CH3 domains that are capable of ADCC and/or ACC.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

Binding domain immunoglobulin fusion proteins were already known before the priority date of the present application. For example, Hayden et al. (Therapeutic Immunol. 94:3-15 (1994) teaches single chain mono- and bi-specific antibody derivatives with novel biological properties and antitumor activity from COS cell transient expression systems; Pastan et al. (USPN 6,147,203; published 11/14/2000); see entire document especially abstract and col. 5-6; Pastan et al. (USPN 6,074,644; published 6/13/2000), see entire document, especially col. 20; Bodmer et al. (USPN 5,677,425; published 10/14/97) see entire document, especially abstract and col. 3-4); Ledbetter et al. (USPN 6,482,919; 11/19/2002, see entire document).

4. As no technical features can be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

5. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-235, 238-348, 350-398, 409, and 413, drawn to a binding domain immunoglobulin fusion proteins comprising a binding domain for a cognate structure such as an antigen, a counter-receptor or the like, a wild-type IgG, IgA or IgE hinge acting region or a mutant IgG1 hinge region having zero, one or two cysteine residues, and immunoglobulin CH2 and CH3 domains that are capable of ADCC and/or ACC, a composition comprising the protein.

Group II, claim(s) 236, 237, 344-349, 410 and 411, drawn to a method of reducing a target cell population in a subject, a method of depleting cells in an animal, a method of treating a subject with the protein.

Group III, claim(s) 399-408, drawn to a polynucleotide encoding a protein comprising a binding domain immunoglobulin fusion proteins comprising a binding domain for a cognate structure such as an antigen, a counter-receptor or the like, a wild-type IgG, IgA or IgE hinge acting region or a mutant IgG1 hinge region having zero, one or two cysteine residues, and immunoglobulin CH2 and CH3 domains that are capable of ADCC and/or ACC, a cell containing the polynucleotide, a vector for expressing the polynucleotide, a method for expressing the protein.

Group IV, claim(s) 412, drawn to a method for displaying recombinant immunoglobulins with heavy chain regions modifications.

6. Two different products are presented in Groups I and III. These two products do not share a common property or activity and do not share common core structures. None of the species of Ig binding proteins require the same exact amino acid sequence, and none of the polynucleotides encoding the Ig binding proteins shares the same nucleotide sequence. The Ig binding proteins are not interchangeable with the polynucleotides and vice versa.

7. Two different methods are presented in Groups II and IV. The methods are not overlapping and not obvious variants. The methods do not rely on the same steps, the same reagents used or share the same intended population.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn Bristol/
Examiner, Art Unit 1643
Temporary Partial Signatory Authority